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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,323	02/16/2007	Daniel Magilavy	253780	2783

23460 7590 12/21/2009

LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6731

EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
12/21/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Chgpatent@leydig.com
Chgpatent1@leydig.com

Office Action Summary	Application No.	Applicant(s)	
	10/588,323	MAGILAVY, DANIEL	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/08/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on 10/08/2009, has been entered.

Applicant's amendment, filed 10/08/2009, has been entered.
Claim 1 has been amended.

Claims 5 and 30 have been canceled previously.

Claims 1-4 and 6-29 are pending

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Office Action will be in response to applicant's arguments, filed 10/08/2009.

The rejections of record can be found in the previous Office Actions, mailed 10/06/2008 and 04/08/2009.

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. This is a New Matter rejection under the provisions of 35 U.S.C. § 112 written description.

Claims 1-4 and 6-22 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide support for the invention as now claimed:
Claim 1. A method of treating a subject who has psoriasis, the method comprising administering a multiple course of treatment of a soluble CD2-binding LFA-3 polypeptide to the subject, wherein the multiple course comprises multiple cycles of treatment, wherein each cycle comprises an administration period *of about twelve weeks* comprising multiple administrations of the soluble CD2-binding LFA3 polypeptide and an interval between administrations, and a rest period, *wherein the interval between administrations is about one week, and wherein the rest period is at least twelve weeks.*

Applicant's remarks, filed 10/08/2009, indicate that support for *these amendments* can be found throughout the specification as filed, notably at Example 1.

However, applicant does not provide sufficient description and direction in the specification as filed for broadly claiming administration periods of *about twelve weeks* and a rest period, *wherein the interval between administrations is about one week, and wherein the rest period is at least twelve weeks*.

In contrast to applicant's reliance upon the specification as filed, including Example 1, the recitation of "about" and "at least" provide for ranges of time with respect to the claimed administration/rest periods, not clearly supported or defined in the specification as filed.

The specification does not provide sufficient blazemarks nor direction for broadly claiming administration/rest periods, as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action

Alternatively, applicant is invited to provide sufficient written support for the *"limitations"* indicated above. See MPEP 714.02 and 2163.06

Applicant's arguments have not been found persuasive

5. Claim 7 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

It is apparent that the pSAB152 plasmid is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the the appropriate plasmid. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, *applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications*.

As noted previously that it was acknowledged that pages 1-2, overlapping paragraph, and pages7-10 of the instant specification appears to rely upon U.S. Patent No. 6,162,432 (1449; #A30) for the deposit of pSAB152 (ATCC 68720),

the record remains not clear whether the conditions for the deposit of biological materials under 35 USC § 112, first paragraph, with respect to the deposit of pSAB152 (ATCC 68720) have been satisfied.

Applicant's Remarks, filed 10/08/2009, does not clearly address this outstanding rejection.

While applicant relies upon the filed ATCC deposit information and upon the reference to issued U. S. Patent No. 6,162,432; applicant has not addressed whether *all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications*. See MPEP 2410.01 and 37 CFR 1.808.

6. Upon reconsideration of applicant's amended claims, filed 10/08/2009, the previous rejection under 35 U.S.C. § 102 (a)(e) as being anticipated by Vaishnaw et al. (US 200401770635) has been withdrawn.

7. Upon reconsideration of applicant's amended claims, filed 10/08/2009; the previous rejection under 35 U.S.C. § 102(a)(b)(e) as being anticipated by Dingivan (US 2003/0044406)(1449; #A1) has been withdrawn.

8. Claims 1-4 and 6-29 are rejected under 35 U.S.C. § 102(a)(b)(e) as being anticipated by Dingivan (US 2003/0068320) (see entire document).

Dingivan teach the treatment of psoriasis (e.g., see paragraphs [0015] – [0022], [0043]-[0067], [0101]-[0103], [0115], [0121]-[0124], [0139], [0261]-[0289])

with CD2 antagonists encompassed by the claimed LFA-3 polypeptides alefacept / AMEVIVE (e.g. paragraphs [0217]-[0258])

with multiple dosing (e.g., Summary of the Invention on pages 3-19; Detailed Description, including paragraphs [0118]-[0127], [0265]-[0289], [[0294]-[0295]),

including weekly and once every 12 weeks administration (e.g., see paragraph [0032]).

Note, too, that Dingivan teaches the PASI score as a means to assess the severity of psoriasis (e.g., see paragraphs [0061]-[0064], [0103], [0121]-[0124], [0264], [0268], [0372]).

With respect to the claimed recitation of multiple cycles comprising administration periods and rest periods, including at least 4-8 cycles, 8-12 weeks and years;

the multiple treatments as described by the prior art anticipate such claims,

given that multiple treatments necessarily require an administration period and a rest period and read on long term treatment to alleviate the severity of the chronic disease of psoriasis.

9. Claims 1-4 and 6-29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Vaishnaw et al. (US 200401770635) AND Dingivan (US 2003/0068320) in view of Magilavy (US 20020009446) (1449; #A3) and as further evidenced by The Merck Manual of Diagnosis and Therapy, Seventeenth Edition (edited by Beers et al., published by Merck Research Laboratories, Whitehouse Station, NJ, 1999; see pages 816-818) essentially for the reasons of record and in view of the newly added reference Dingivan (US 2003/0068320)

Applicant's arguments, filed 10/08/2009, have been considered but have not been found convincing essentially for the reasons of record and in view of the newly added reference Dingivan (US 2003/0068320).

As noted above, newly added Dingivan (US 2003/0068320) (see entire document) teaches the following.(see entire document).

Dingivan teach the treatment of psoriasis (e.g., see paragraphs [0015] – [0022], [0043]-[0067], [0101]-[0103], [0115], [0121]-[0124], [0139], [0261]-[0289])

with CD2 antagonists encompassed by the claimed LFA-3 polypeptides alefacept / AMEVIVE (e.g. paragraphs [0217]-[0258])

with multiple dosing (e.g., Summary of the Invention on pages 3-19; Detailed Description, including paragraphs [0118]-[0127], [0265]-[0289], [[0294]-[0295]),

including weekly and once every 12 weeks administration (e.g., see paragraph [0032]).

Note, too, that Dingivan teaches the PASI score as a means to assess the severity of psoriasis (e.g., see paragraphs [0061]-[0064], [0103], [0121]-[0124], [0264], [0268], [0372]).

With respect to the claimed recitation of multiple cycles comprising administration periods and rest periods, including at least 4-8 cycles, 8-12 weeks and years;

the multiple treatments as described by the prior art anticipate such claims,

given that multiple treatments necessarily require an administration period and a rest period and read on long term treatment to alleviate the severity of the chronic disease of psoriasis.

While applicant argues that the prior art, particularly Vanishaw et al. and Dingivan do not teach a rest period of at least twelve week, as identified in the instant claims as amended.

In contrast to applicant's assertions, newly added Dingivan et al. teach modes of administration, including multiple dosing (e.g., Summary of the Invention on pages 3-19; Detailed Description, including paragraphs [0118]-[0127], [0265]-[0289], [[0294]-[0295]), as well as dosing including weekly and once every 12 weeks administration (e.g., see paragraph [0032]).

Also, note that Magilavy teach weekly administration of LFA3TIP for 12 weeks with a followup for and after 12 weeks in Examples 1 and V, including for endpoints associated with psoriasis (see Example V) on pages 14 and 17-19.

Given the prior art teachings encompassing multiple treatments via intramuscular and intravenous administration, including administration on a weekly basis for 12 weeks or at 12 week intervals as well as followup analysis after 12 weeks on a chronic disease such as psoriasis, in addition to the teachings that the ordinary artisan relied upon the PASI score as a means to assess the severity of psoriasis (e.g., see paragraphs [0028], [0123] – [0125], [0402], [0495], [0554]);

the ordinary artisan necessarily would have relied upon an administration period and a rest period, wherein the rest period can be "at least twelve weeks".

Again, and in response to applicant's arguments, the following teaching of known practices in the treatment of psoriasis by the ordinary artisan at the time the invention was made has been added.

Coupled with these teachings is the chronic nature of psoriasis itself, where the disease encompasses acute attacks, permanent remission is rare and no therapy is curative (e.g., see The Merck Manual of Diagnosis and Therapy, Seventeenth Edition, edited by Beers et al., published by Merck Research Laboratories, Whitehouse Station, NJ, 1999; see pages 816-818).

As indicated previously to the use of multiple courses of administering LFA-3 polypeptides for a chronic disease such as psoriasis and as would be applicable to the current amended claims, such dosing and modes of administration are result effective variables.

It is well settled that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). See also Merck & Co. v. Biocraft Labs. Inc., 874 F.2d 804, 809, 10 USPQ2d 1843, 1847-48 (Fed. Cir. 1989) (determination of suitable dosage amounts in diuretic compositions considered a matter of routine experimentation and therefore obvious).

As dosing and modes of administration are known to the ordinary artisan, it would have been obvious to optimize both the dosing regimens and mode of administration to meet the needs of the patient at the time the invention was made.

Given the clear teachings of the prior art to treat psoriasis with immunosuppressive LFA-3 polypeptides in order to meet the needs of the patients, including teachings of multiple dosing and therapeutic endpoints of reducing the severity of a chronic disease as well as reliance upon criteria such as PSAI scores;

one of ordinary skill in the art at the time the invention was made would have been motivated to administer immunosuppressant LFA-3 polypeptides over long periods of time, including weeks and years, including intervals and followup analysis at 12 weeks, in order to treat a chronic disease such as psoriasis.

The various dosing regimens encompassed by the instant claims were obvious at the time the invention was made, given that it was well known and practice at the time the invention was made to provide immunosuppressive therapy based upon the condition and needs of the patient, as evidenced by the teachings of the prior art.

The following is reiterated herein for applicant's convenience.

Vaishnaw et al. teach the LFA-3 polypeptide (alefacept, AMEVIVE; see entire document) of the claimed invention (e.g., see paragraphs [0130] – [0156]) (also see AMEVIVE in paragraph [0203] and plasmid in [0209] 0 [0220],
for the treatment of skin disorders, including psoriasis (e.g. paragraph [0002]- [0005], [0012]-[0014], [0028] [0040] –[0066], [0177]-[0183]
encompassing multiple treatments via intramuscular and intravenous administration (e.g., see paragraphs [0050] – [0058], [0175] - [0181] and
including kits and instructions comprising the LFA-3 polypeptide to treat psoriasis (e.g. paragraphs [0072] and [0196] – [0197] (see entire document)..

Note that Example 3 of Vaishnaw incorporates PASI improvement in the determination of correlating effective treatment by alefacept / AMEVIVE (e.g., see Example 3 on paragraphs [0203] – [0206]

Magilavy teach the use of the CD2 binding agents of the claimed invention (e.g., LFA3TIP, see pages 20-26 and page 38) for the treatment of inflammatory conditions
that can be administered in dosing and modes of administration that appear to be the same or nearly the same as claimed, such that the dosing and modes of administration are continued until the desired effect is achieved (e.g., see pages 30-33) (see entire document).

Although Magilavy does not disclose psoriasis per se, Magilavy does teach psoriatic arthritis and dermatitis and inflammatory conditions associated with T cells, which is consistent with the inflammatory conditions associated with psoriasis (e.g., see Summary of the Invention on pages 5-6). Note, too, that Magilavy recognizes that PSAI scores as well as nail evaluation are assessed with skin lesions by the dermatologist for efficacy (e.g., see Example V on pages 46-52, including page 50).

With respect to the recitation of multiple cycles comprising administration periods and rest periods and long term treatment,
the multiple treatments described by the prior art render obviousness such claims,
given that multiple treatments necessarily require an administration period and a rest period and are required over a long time in order to alleviate the chronic disease of psoriasis.

As to the use of multiple courses of administering LFA-3 polypeptides for a chronic disease such as psoriasis,
such dosing and modes of administration are result effective variables.

It is well settled that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). See also Merck & Co. v. Biocraft Labs. Inc., 874 F.2d 804, 809, 10 USPQ2d 1843, 1847-48 (Fed. Cir. 1989) (determination of suitable dosage amounts in diuretic compositions considered a matter of routine experimentation and therefore obvious).

As dosing and modes of administration are known to the ordinary artisan, it would have been obvious to optimize both the dosing regimens and mode of administration to meet the needs of the patient at the time the invention was made.

Given the clear teachings of the prior art to treat psoriasis with immunosuppressive LFA-3 polypeptides in order to meet the needs of the patients, including teachings of multiple dosing and therapeutic endpoints of reducing the severity of a chronic disease as well as reliance upon criteria such as PSAI scores;

one of ordinary skill in the art at the time the invention was made would have been motivated to administer immunosuppressant LFA-3 polypeptides over long periods of time, including weeks and years, in order to treat a chronic disease such as psoriasis.

The various dosing regimens encompassed by the instant claims were obvious at the time the invention was made, given that it was well known and practice at the time the invention was made to provide immunosuppressive therapy based upon the condition and needs of the patient, as evidenced by the teachings of the prior art.

With respect to the kit, the recitation of "a patient who has previously had two cycles of treatment with AMEVIVE" does not patentable weight to the claimed "kit", in the absence of providing some structural distinction over the prior art compositions.

A composition is a composition irrespective of what its intended use is.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to inhibit immune responses in patients with psoriasis with immunosuppressant LFA-3 polypeptides,

incorporating multiple courses of immunosuppressant LFA-3 over a long time would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in designing such methods to effectively treat, manage or ameliorate a chronic disease / condition such as psoriasis.

Applicant's arguments have not been found persuasive.

10. Claims 1-4 and 6-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 64-75 of USSN 11/398,908 for the reasons of record.

Applicant's arguments, filed 10/08/2009, concerning the pending status of the instant and copending applications as well as the issue that the instant application is the earlier filed applicaiton have been fully considered but have not been found convincing essentially for the reasons of record.

In contrast to applicant's assertions, the instant application is not in condition for allowance.

The obviousness-type double patenting rejection is maintained for the reasons of record.

Although the copending claims differ in the targeted diseases, all of the claims rely upon the same AMEVIVE, LFA-3 antagonists to treat inflammatory conditions, including psoriasis in the instant application and psoriatic arthritis and dermatitis in the copending application. Modes of administration and dosing are obvious over one another in that the ordinary artisan would have provided the appropriate effective amounts to achieve therapeutic end results of reducing severity of an inflammatory condition, including the chronic inflammatory conditions encompassed by the claimed methods. Therefore, treating the various inflammatory conditions with the same LFA-3 antagonists would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/
Primary Examiner
Technology Center 1600
Art Unit 1644
December 3, 2009